Message

From: Strauss, Linda [Strauss.Linda@epa.gov]
Sent: 9/27/2017 9:56:48 PM
To: Beck, Nancy [Beck.Nancy@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]
CC: Jakob, Avivah [Jakob.Avivah@epa.gov]; Keigwin, Richard [Keigwin.Richard@epa.gov]
Subject: FW: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK

Ex. 5 - Deliberative Process

OPP is working to answer the Q's below in yellow. We'll get the FDA listserv and their Q's and A's tomorrow to review. If their FR doesn't publish on Friday, they'll still go out with it. Not exactly sure what's driving the tight schedule – could be the hurricane and the feeling that companies want mosquito registrations? Not sure.

Linda

From: Norris, Anne
Sent: Wednesday, September 27, 2017 4:42 PM
To: Strauss, Linda; StClair, Christie; Valentine, Julia; 'Daguillard, Robert'; Putnam, Juli
Cc: Nalubola, Ritu; Flamm, Eric; Epstein, Laura
Subject: GE Mosquito Final Guidance Announcement HAPPENING THIS WEEK
Importance: High

Hi Linda,

We just learned that this final guidance is on an EXTREMELY fast trajectory and we're almost certainly going to be announcing by this Friday (9/29). Unfortunately, our communications documents are still in clearance and it would be premature to send them to you in case edits still need to be made. At this point, we should be able to share tomorrow, but it's unclear at what time.

We will share our CVM Update and Responsive QAs at the earliest point possible; however, if you wait until after you view our comms to start developing your QAs or talking points, you won't be allowing yourselves adequate time. Additionally, our responsive QAs are primarily geared toward addressing the questions that the FDA anticipates getting, which won't be very helpful for EPA's needs when it comes to questions that will be directed to EPA from media and stakeholders. Of particular sensitivity right now is the issue of mosquitoes and hurricane relief.

Given the short timeframe, we would strongly suggest that you and your team consult with the EPA policy team working on this issue to get their thoughts on what issues/questions they expect to arise and how they would advise you to handle them. My understanding is that those people are Bob McNally, Elizabeth Milewski, and Mike Mendelsohn.

As Juli had previously mentioned, some examples of the types of questions you might get could be things like:
-What further regulation will the sponsor have to go through to conduct field trials in jurisdictions within the US or to get a commercial approval for the mosquitoes? Will EPA rely on the data the sponsor already provided to the FDA? How long will the process take?
-Do you have any applications/permits/whatever the correct terminology is from Oxitec in house that you are currently reviewing?
-Does the EPA have comment on FDA's guidance? Will this delay the approval/permitting of Oxitec's GE mosquitoes to Hurricane-stricken areas?

Please keep in touch with questions and concerns – feel free to call me anytime at 240-402-0132. We'll reach out tomorrow about the status of our communications and to set up a call with you, if needed.

Thanks,
Anne

Anne Norris
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